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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:	
YASUSHI NAKADA, ET AL.	:	EXAMINER: SHIAO, REI TSANG
SERIAL NO: 10/516,320	:	
FILED: DECEMBER 13, 2004	:	GROUP ART UNIT: 1626
FOR: PHARMACEUTICAL COMPOSITION FOR IMPROVING CEREBRAL FUNCTION AND METHOD FOR IMPROVING CEREBRAL FUNCTION	:	

RESTRICTION RESPONSE AND ELECTION OF SPECIES

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

In response to the Election/Restriction Requirement dated March 20, 2007, Applicants elect, with traverse, Group III, Claims 1-8 for examination.

As a single disclosed species, Applicants elect Compound A3 (1-[3-(2-(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol) and Compound B1 (Donepizil) for examination purposes only.

REMARKS/ARGUMENTS

The claims have been divided into Groups as follows:

Group I: Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is T-588 thereof (compound A1, i.e., the variable R1 represents heterocyclic group selected from benzothiazole thereof) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R^3 and R^4 form a piperidine); or drawn to a pharmaceutical composition comprising

ingredients (A), wherein the ingredients (A) is T-588 thereof (compound A1, i.e., the variable R^1 represents heterocyclic group selected from benzothiazole thereof) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making.

Group II: Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 2- [[3- (2-benzo[b]thiophen-5-yl-ethoxy)propyl] (methyl)amino] -1-ethanol. ½ fumarate thereof (compound A2) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R^3 and R^4 form a piperidine); or drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 2- [[3- (2-benzo[b]thiophen-5-yl-ethoxy)propyl] (methyl)amino] -1-ethanol. ½ fumarate thereof (compound A2) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making.

Group III: Claims 1-8, in part, drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 1-[3-(2(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol thereof (compound A3) and the ingredients (B) is Donepezil thereof (compound B1, i.e., the variable R^3 and R^4 form a piperidine); or drawn to a pharmaceutical composition comprising ingredients (A), wherein the ingredients (A) is 1-[3-(2(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol thereof (compound A3) and the ingredients (B) is Tacrine thereof (compound B2), and their processes of making.

Group IV: Claim 1-8, in part, drawn to a pharmaceutical composition, containing compounds or ingredient (A) or (B) not encompassed in Groups I-III.

In addition an election of a single-disclosed specie from the elected Group is required.

Applicants elect, with traverse, Group III, Claims 1-8 for examination.

As a single disclosed species, Applicants elect Compound A3 (1-[3-(2-(1-benzothiophen-5-yl)ethoxy)-propyl]-3-azetidinol) and Compound B1 (Donepizil) for examination purposes only.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). Moreover, when citing lack of unity of invention, in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other (MPEP §1893.03(d)), i.e. why there is no single general inventive concept. The presence of no single inventive concept must be specifically described.

The Examiner has indicated that the application contains a group of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1, since under PCT Rule 13.2:

> "the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, . . . Moreover, the claimed compounds/compositions of the formula of claim 1 contains different common structures or different special technical features, i.e., compounds having various moieties (i.e., morpholine, piperidine or pyrrolidine)."

Annex B of the Administrative Instructions under the PCT at (b) Technical Relationship states:

> "The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any)."

Applicants respectfully submit that the Examiner has not provided any indication that the contents of the claims interpreted in light of the description was considered in making the assertion of a lack of unity and therefore has not met the burden necessary to support the assertion.

Moreover, MPEP § 1850 (B) "*Markush Practice*" states:

> "When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of similar nature where the following criteria are fulfilled:
> (A)All alternatives have a common property or activity; and
> (B)(1) A common structure is present, i.e., a significant structural element is shared by all the alternatives;"

Applicants respectfully submit that in the above identified application, the compounds of the formula in Claim 1 do have the common activity as defined in Claim 1 and therefore meet criterion (A).

Relative to criterion (B)(1) MPEP § 1850 (B) defines "significant structural element is shared by all the alternatives" as "cases where the compounds share a common chemical

structure which occupies a large portion of their structures." Moreover the PCT in the PCT International Search and Preliminary Examination Guidelines provide guidance in this matter through example analysis. Applicants respectfully submit that Example 18 on page 84 of the document is a suitable reference relative to analysis of the formula of Claim 1. Applicants submit that the compounds of the formula in Claim 1 all share the common structure of an aminoalkyl ether as indicated in the formula and that this common structure occupies a sufficient portion of the structure to meet criterion (B)(1).

Because the compounds of the formula meet the criteria of (A) and (B)(1) above, Applicants submit that the claims of the above-identified application relate to a single general inventive concept under PCT Rule 13.1 and therefore unity of invention is not lacking.

Applicants respectfully traverse the Restriction Requirement on the grounds that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups.

For the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the Restriction Requirement. Withdrawal of the Restriction Requirement is respectfully requested.

Applicants submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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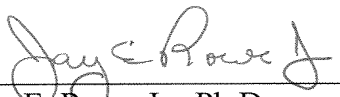
MAIER & NEUSTADT, P.C.
Norman F. Oblon



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